IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH,	)	
Plaintiffs,	)	
v.	)	C.A. No. 22-252-MSG
MODERNA, INC. and MODERNATX, INC.,	)	
Defendants.	)	

PLAINTIFFS' OPPOSITION TO DEFENDANTS' PARTIAL MOTION TO DISMISS

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I. INTRODUCTION

Though the COVID-19 pandemic has caused immeasurable human suffering and economic devastation, one company has benefited uniquely from this health crisis, transforming from an impecunious, product-less biotechnology company to a fifty-billion-dollar behemoth that has enriched its shareholders and executives enormously. That company, Moderna, requested and received over a billion dollars in grant assistance from the U.S. government[1] for its efforts to develop a COVID-19 vaccine, which it did by employing key technology invented and patented by others. Moderna then sold hundreds of millions of doses of its infringing COVID-19 vaccine to the U.S. government, for the purpose of distribution to, and use by, the U.S. population as a whole. Having leveraged government grant money to realize eighteen billion dollars in sales in 2021 alone,[2] Moderna was still not satisfied. When the bill for its willful patent infringement came due, by way of this lawsuit asserting, among others, patents that Moderna spent the last three years attempting to invalidate before two different tribunals, Moderna's response was not to accept responsibility or to defend its product or conduct on the merits. Rather, Moderna moved to dismiss part of this case on the misguided basis that, though the billions it received in grants and payments from the U.S. government and credit for the vaccine belong to Moderna and its executives alone, the liability for its blatant patent infringement belongs to the U.S. government.

The law does not countenance that result; it forecloses it. Remarkably, Moderna seeks partial dismissal without citing a shred of authority for the proposition that the requirement of 28 U.S.C. § 1498(a) that the infringement be "for the government" is satisfied where, as here, the U.S. government purchases a product for distribution to, and the benefit of, the population as a whole,

[1] *See* Moderna 2021 10-K (2022), at 41. The facts and materials cited in this paragraph are for context only; they are not evidence Plaintiffs ask the Court to consider to decide this motion.
[2] *See id.* at 19.

rather than for the benefit of the U.S. government itself. Even more remarkably, Moderna does not even acknowledge, let alone seek to distinguish, precedent holding squarely that U.S. government-funded sales of a medical product are ***not*** "for the government," and therefore not subject to a defense under section 1498(a), when the government pays for the product for the benefit of the population as a whole rather than for the government itself. Rather than address this precedent that compels denial of its motion, Moderna relies, improperly, on redacted government contracts and cases that do not even implicate the statutory framework at issue—materials that cannot justify partial dismissal as a matter of law. Moderna's motion should be denied.

II. NATURE AND STAGE OF PROCEEDINGS

On February 28, 2022, Plaintiffs Arbutus Biopharma Corporation ("Arbutus") and Genevant Sciences GmbH ("Genevant") filed a Complaint against Defendants Moderna, Inc. and ModernaTX, Inc. (collectively, "Moderna") seeking damages for Moderna's willful infringement of several patents related to the crucial lipid nanoparticle technology used in Moderna's COVID-19 vaccine. D.I. 1. On May 6, Moderna filed a partial motion to dismiss some unidentified subset of Plaintiffs' claims that relate to sales to the U.S. government pursuant to 28 U.S.C. § 1498(a).

III. SUMMARY OF ARGUMENT

Whatever section 1498(a) was enacted to promote, it certainly is not Moderna's unprecedented request to shift liability to the U.S. government for vaccine doses administered to private citizens in CVSs, Walgreens, and private medical practices throughout the country. That defense cannot apply unless Moderna satisfies both prongs of section 1498(a)'s two-part test: that the "use or manufacture" of its U.S.-funded vaccine doses was (i) "for the Government" and (ii) with the "authorization or consent" of the government. *See IRIS Corp. v. Japan Airlines Corp.*, 769 F.3d 1359, 1362 (Fed. Cir. 2014). Because section 1498(a) is an affirmative defense, Moderna

bears the burden of establishing both prongs and, at the pleading stage, it must do so based solely on allegations in the Complaint and information amenable to judicial notice.

Moderna cannot meet its burden at all, much less at the pleading stage. On the "for the government" prong, the Complaint alleges that "Moderna's vaccine doses made in the United States and administered in the United States were distributed to hospitals, pharmacies, clinics, and numerous other entities ***for the benefit of individual vaccine recipients in the United States***. All of the manufacturing and sales of vaccines distributed in the United States were ***for the benefit of the American public***." D.I. 1 ("Compl.") ¶ 51 (emphasis added). Moderna ignores these allegations entirely, even though they are controlling at the motion to dismiss stage. *See DelRio-Mocci v. Connolly Properties Inc*., 672 F.3d 241, 245 (3d Cir. 2012); *O'Donnell v. United States*, No. CIV.A. 04-00101, 2006 WL 166531, at *7 (E.D. Pa. Jan. 20, 2006) (denying motion to dismiss where "the allegations in the complaint, which are controlling at this juncture of the litigation, are to the contrary [of defendant's claims]."). Moderna's position seems to be that the Complaint somehow is irrelevant and that such doses were "for the government" because the government funded them. But that is no more true than it would be for medical treatments purchased for elderly and low-income Americans through Medicare and Medicaid, which a court has concluded is not "for the government" under section 1498(a). *Larson v. United States*, 26 Cl. Ct. 365, 371 (1992).

Even setting aside this infirmity fatal to Moderna's motion, Moderna fails to address the particular allegations of infringement in the Complaint. Those allegations are not limited to the ***sale*** of vaccine doses, but also allege that Moderna infringed by inducing the ***use*** of its infringing COVID-19 vaccine by healthcare professionals and vaccine recipients. Compl. ¶ 16. As to these acts of infringement—use by nurses and pharmacists injecting individuals at nongovernment facilities, like Walgreens, across the nation—the government is nowhere to be found, and the

notion that the infringement is "for the government" in those instances is that much more specious.

Moderna attempts to meet the "authorization or consent" prong by using a heavily redacted copy of its contract with the government that it attaches to its motion. That document is incomplete, devoid of context, and not properly amenable to judicial notice on a motion to dismiss.

As with other affirmative defenses, the Federal Circuit has made clear that "a defense arising under section 1498(a) should be resolved by summary judgment under Rule 56 rather than a motion to dismiss under Rule 12," upon a full factual record. *Toxgon Corp. v. BNFL, Inc.*, 312 F.3d 1379, 1382 (Fed. Cir. 2002). That admonition—also ignored by Moderna—applies more forcefully here, where Moderna's motion ***would not streamline or remove any issue in the case***. By filing a partial motion to dismiss, Moderna acknowledges that, even under its flawed legal framework, not all of its acts of infringement are covered by section 1498(a). The litigation over the remaining doses, which Moderna agrees are not subject to its motion, involves the same issues of infringement, willfulness, validity, and damages as the doses that are subject to its motion.

Section 1498 is not an "insurance plan" for companies that deliberately infringe others' patents for their own benefit. *Riles v. Amerada Hess Corp.*, 999 F. Supp. 938, 940 (S.D. Tex. 1998). This Court should reject Moderna's attempt to make it so and deny its motion.

IV. STATEMENT OF FACTS

A. mRNA Vaccines

Moderna's COVID-19 vaccine belongs to a cutting-edge class of medicines that rely on the delivery of bits of messenger ribonucleic acid (mRNA) to the body's cells to instruct them to make certain proteins. Compl. ¶ 2. mRNA-based medicines have long shown great promise but have proven particularly difficult to develop. *Id.* ¶ 3. By their nature, mRNA molecules are fragile and, without adequate protection, quickly degrade in the body. *Id.* For mRNA vaccines like Moderna's to work, they must incorporate a mechanism for protecting the fragile mRNA,

delivering it through cell membranes, and then releasing it inside the cell. *Id.* In the words of one Nobel Prize winning scientist, the secret for making RNA-based products work has always been "delivery, delivery, delivery." *Id.* (citation omitted).

B. Plaintiffs and The Asserted Patents

Through years of painstaking effort and investment, scientists at Arbutus eventually found a solution to the mRNA delivery challenge that had vexed experts for years: microscopic particles formed from fat-like molecules—called lipid nanoparticles, or LNPs—which shelter and protect the mRNA and ensure that it is properly released inside target cells. *Id.* ¶¶ 1, 4.

For its groundbreaking work, the United States Patent and Trademark Office (PTO) awarded Arbutus a number of patents, including the six patents asserted here. *Id.* ¶¶ 4, 9. These patents claim nucleic acid-lipid particles and lipid vesicles, as well as compositions and methods of using them. *Id.* ¶¶ 9, 29. Arbutus has licensed Exclusive Rights to sublicense, practice, and sue for infringement of these patents to Plaintiff Genevant (a company spearheaded by former Arbutus scientists) in certain fields that include the vaccine application at issue here, with certain exceptions not relevant to this case. *Id.* ¶¶ 9, 30.

C. Moderna's Knowledge of Plaintiffs' LNP Patents

Moderna has long been aware of Arbutus's LNP-related patents. *Id.* ¶ 6. In 2015, Moderna attempted to acquire rights to Arbutus's LNP delivery technology through a sublicense from a company called Acuitas Therapeutics. *Id.* ¶ 32. Acuitas had licensed Arbutus's LNP technology in 2012 under a license agreement that expressly limited Acuitas's ability to grant sublicenses. *Id.* That limitation prohibited Acuitas from granting the sublicense that it granted to Moderna. *Id.*

After learning of the Moderna-Acuitas sublicense agreement in August 2016, Arbutus and Acuitas engaged in legal proceedings in Canada to address whether Acuitas's sublicense to Moderna constituted a breach of the Arbutus-Acuitas agreement. *Id.* ¶ 33. The parties eventually

reached a settlement that barred Moderna from using Arbutus's LNP technology, except for four specific sublicenses for vaccines targeting specific viruses. SARS-CoV-2, the virus that causes COVID-19, is not among those surviving sublicenses. *Id.* ¶ 34.

Deprived of a broad license to use Arbutus's valuable LNP technology and hoping to use the technology without paying royalties, Moderna began filing *inter partes* review (IPR) petitions requesting that the PTO cancel Arbutus's patents, including some of those asserted here. *Id.* ¶ 35. The PTO rejected many of Moderna's arguments and the U.S. Court of Appeals for the Federal Circuit rejected Moderna's attempts to reverse those decisions. *Id.* ¶¶ 37, 38. Thus, the validity of many of the claims asserted in this case already has been confirmed by both the PTO and Federal Circuit. *Id.* Moderna's unsuccessful challenges have a clear and important consequence in this case: Moderna now cannot raise any invalidity defense in this case that it raised or could have raised in those proceedings. 35 U.S.C. § 315(e)(2).

D. Moderna's Unauthorized Use of Plaintiffs' LNP Technology

Several years after Moderna filed its first IPR petition, with the novel SARS-CoV-2 virus quickly spreading around the world, scientists identified the virus's complete genetic sequence and posted it on the internet. Compl. ¶ 39. With that information, pharmaceutical companies, including Moderna, began developing a COVID vaccine. *Id.* ¶ 40. Relying on Arbutus's LNP technology covered by the Asserted Patents, Moderna was able to begin producing its COVID-19 vaccine ***within just a few days*** of the SARS-CoV-2 sequence entering the public domain. *Id.* ¶ 41.

Moderna was successful on such an unprecedented timeline because it used LNP technology that was covered by Plaintiffs' patents, as Moderna knew. *See id.* ¶¶ 6-9, 39-50. That technology is no small part of the vaccine's success, either. *See id.* ¶ 5. LNPs identified through Arbutus's pioneering work have been described as "crucial" to Moderna's COVID-19 vaccine. *Id.* Without the LNPs Arbutus invented to safeguard the mRNA and deliver it into cells, the mRNA

in Moderna's vaccine would degrade before ever reaching the cells it needs to enter, and the vaccine would not work. *Id.*

After FDA authorized emergency use of Moderna's COVID-19 vaccine on December 18, 2020, Moderna began distributing doses in the United States and around the world. *Id.* ¶ 51. As the Complaint alleges, these vaccine doses were distributed to hospitals, pharmacies, clinics, and numerous other entities for the benefit of individual vaccine recipients in the United States. *Id.* Although some of these doses were paid for by the U.S. government, all of the manufacturing and sales of vaccines distributed in the United States were for the benefit of the American public. *Id.*

Since that time, Moderna has enjoyed incredible financial success, virtually entirely based on sales of its COVID-19 vaccine. In 2021, Moderna shipped 807 million doses of its COVID-19 vaccine. *Id.* As of February 24, 2022, Moderna had signed advanced purchase agreements worth approximately $19 billion for all of 2022. *Id.* As of May 6, 2021, Moderna had signed advance purchase agreements covering more than one billion doses. *Id.*

E. Acts of Infringement Alleged in the Complaint

The Complaint alleges various distinct acts of infringement that Moderna's motion improperly aggregates. The Complaint alleges that Moderna infringed directly, and continues to infringe directly, by manufacturing its vaccine with LNPs covered by the asserted patents for distribution to the American people. *Id.* ¶¶ 70, 89, 108, 130, 154, 173. The Complaint further, and separately, alleges that Moderna has and continues to engage in indirect infringement. That is, Moderna "actively, knowingly, and intentionally has induced, and continues to induce" infringement of the asserted patents by "encouraging others to make and use" its infringing vaccine, *id.* ¶¶ 71, 90, 109, 131, 155, 174, and Moderna has "contributed, and continues to contribute, to" others' infringement of the asserted patents, *id.* ¶¶ 72, 91, 110, 132, 156, 175. Specifically, the Complaint alleges that Moderna induces infringement by individuals who receive

Moderna's vaccine and the healthcare professionals who administer vaccines doses to those individuals. *Id.* ¶¶ 78-79, 97-98, 119-20, 143-44, 162-63, 182-83.

V. LEGAL STANDARD

When deciding a motion to dismiss under Rule 12(b)(6), the Court must "accept as true all allegations in the complaint and all reasonable inferences that can be drawn therefrom, and view them in the light most favorable to the plaintiff." *Evancho v. Fisher*, 423 F.3d 347, 350 (3d Cir. 2005); *Host Int'l, Inc. v. MarketPlace, PHL, LLC*, 32 F.4th 242, 248 (3d Cir. 2022) ("Surviving a motion to dismiss requires 'only enough facts to state a claim to relief that is plausible on its face.'" (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007))). "A motion to dismiss pursuant to 12(b)(6) may be granted 'only if, accepting all well-pleaded allegations in the complaint as true and viewing them in the light most favorable to the plaintiff, a court finds that plaintiff[']s claims lack facial plausibility.'" *DelRio-Mocci v. Connolly Properties Inc*., 672 F.3d 241, 245 (3d Cir. 2012) (quotation omitted).

"To decide a motion to dismiss, courts generally consider only the allegations contained in the complaint, exhibits attached to the complaint and matters of public record." *Schmidt v. Skolas*, 770 F.3d 241, 249 (3d Cir. 2014). With respect to a contract with a government entity, "[a]lthough that document may be public[ly] available," such a document "goes beyond the type of matter of public record that a court can consider in a motion to dismiss." *Campbell v. Doe*, No. CV 12-2750 (SDW), 2017 WL 349289, at *3 (D.N.J. Jan. 24, 2017) (citing *Schmidt*, 770 F.3d at 249).

A court also may "judicially notice a fact that is not subject to reasonable dispute." Fed. R. Evid. 201(b). While courts can take judicial notice of the fact or existence of a document or its contents, the "truth of the content, and the inferences properly drawn from them . . . is not a proper subject of judicial notice under Rule 201." *IV Sols., Inc. v. United HealthCare Servs., Inc.*, No.

CV1609598MWFAGRX, 2017 WL 3018079, at *2 (C.D. Cal. July 12, 2017); *Network Managing Sols., LLC v. AT&T Inc.*, No. CV 16-295-RGA-MPT, 2017 WL 5195863, at *4 (D. Del. Nov. 9, 2017), *report and recommendation adopted sub nom. Network Managing Sols., LLC v. AT&T Mobility, LLC*, No. CV 16-295-RGA, 2017 WL 11553316 (D. Del. Dec. 1, 2017) ("Taking judicial notice of the truth of the documents' contents could breach the boundaries of judicial notice.").

In addition, courts regularly decline to take judicial notice of redacted documents because "redactions make[] it difficult to evaluate the contract holistically." *IV Sols., Inc.*, 2017 WL 3018079, at *3; *see also Delgado v. ILWU-PMA Welfare Plan*, No. CV 2:18-CV-5539 CBM, 2019 WL 2864427, at *2 (C.D. Cal. Apr. 26, 2019) (denying judicial notice of "highly redacted" documents where parties "hotly-dispute[d] many of the facts allegedly established" by the documents); *Se. Ready Mix, LLC v. Argos N. Am. Corp.*, No. 1:17-CV-02792-ELR, 2018 WL 8263138, at *9 n.13 (N.D. Ga. Aug. 22, 2018) ("[T]he Court declines to take judicial notice of the contents of the Agreement as the attached version is heavily redacted.").

VI. ARGUMENT

A. Moderna Has Not and Cannot Establish, Particularly at the Pleading Stage, That the Acts of Infringement Alleged in the Complaint Were "For the Government" Under 28 U.S.C. § 1498(a)

1. An Infringing Act is Not "For the Government" Under Section 1498(a) Unless the Government Itself was a Direct Beneficiary

Section 1498 is a World War I-era statute enacted to ensure that the government could procure and use weapons that met the military's particular specifications and requirements. *See Madey v. Duke University*, 413 F. Supp. 2d 601, 606 (M.D.N.C. 2006) (citing *Richmond Screw Anchor Co. v. United States,* 275 U.S. 331, 345 (1928)). Under 1498(a), a "use is 'for the Government' if it is 'in furtherance and fulfillment of a stated Government policy' which serves the Government's interests and which is 'for ***the Government's*** benefit.'" *Japan Airlines*, 769

F.3d at 1362 (quoting *Madey*, 413 F. Supp. 2d at 607) (emphasis added). To qualify, the government benefit must be direct. *Id.* ("[I]ncidental benefit to the government is insufficient . . . ."). Thus, "[w]hen the Government authorizes an 'action' by a third party, it is not therefore liable for *any* infringement the third party may choose to undertake within the sphere of the authorized activity," but rather only for infringement "actually done for the United States Government." *Riles*, 999 F. Supp. at 941. "[T]he purpose of § 1498 dictates that its strongest protection should be extended to contractors who sell military goods to the government"—for use by the government. *Saint-Gobain Ceramics & Plastics, Inc. v. II-VI Inc.*, 369 F. Supp. 3d 963, 976 (C.D. Cal. 2019).

Applying these principles, the United States Claims Court[3] held in *Larson v. United States* that the government's payment for medical products for use by American citizens is not "for the government" under section 1498(a)—even where the government "funds or reimburses all of part of" their cost. 26 Cl. Ct. at 369. There, the issue was whether the government was liable for a private contactor's patent infringement in making splints and casts paid for by Medicare. The court held it was not: "Medical care is provided for the benefit of the patient, not the government," and so the "use of plaintiffs' casts and splints was for the benefit and convenience ***of the patient and provider, with no benefit to the government***." *Id.* (emphasis added).

It is telling that Moderna does not even acknowledge *Larson*, a case that addresses squarely the crucial issue here—whether the government's payment for medical care products used by individual citizens constitutes infringement "for the government" under section 1498(a). Indeed, not a single case Moderna cites involves that inquiry. The fact that *Larson* involved a statutory scheme where the government reimbursed, rather than directly purchased, the medical products at

[3] Now called the Court of Federal Claims. *See In re Chandler*, 56 F.3d 80 (Fed. Cir. 1995).

issue was immaterial to the court's reasoning. The court held that medical care provided for citizens is not "for the government" under section 1498(a) regardless of whether the government "***funds*** or reimburses" its cost. 26 Cl. Ct. at 369 (emphasis added). And, just as in *Larson*, where the government "neither require[d], recommend[ed], nor suggest[ed] that providers use particular types, models, or brand names of casts and splints," *id.* at 367, there is no evidence that the government here required or recommended that Americans opt for Moderna's COVID-19 vaccine over any other FDA-authorized or approved option.

Outside of the medical-care context, courts regularly hold that a government's policy interest underlying a purchase of goods—even if important—does not render such purchase "for the government" under section 1498(a). In *Windsurfing International, Inc. v. Ostermann*, the court held that the U.S. Olympic Committee's purchase and use of a patented sailboard for the U.S. windsurfing team was not a use "for the government" because "[w]hile the United States has great interest in the running of the Olympics generally," "[t]his indirect interest is simply too remote from the purposes underlying § 1498 to support the conclusion that the use of sailboards . . . is use 'for' for the United States entitling the patentee to sue the government for compensation." 534 F. Supp. 581, 588 (S.D.N.Y. 1982). Likewise, in *Carrier Corporation v. United States*, the court held that a government contractor's use of a patented device to remove refuse was not a use "by the Government" because "if there was any use of plaintiff's patented invention, such use was by the contractor and not by the Government." 534 F.2d 244, 247 (Ct. Cl. 1976). And in *Riles v. Amerada Hess Corporation*, the court held that the fact the government received a royalty from defendant's oil-drilling activities on federal land did not render defendant's use of a patented drilling method "for the government" under section 1498(a). 999 F. Supp. 938, 940 (S.D. Tex. 1998). Rather, even though the royalty benefited the government, that benefit was incidental and

did not render the accused infringement itself "for the government." *See id.*; *see also Sheridan v. United States*, 120 Fed. Cl. 127, 131, *aff'd*, 629 F. App'x 948 (Fed. Cir. 2015) ("Where benefits to the Government are merely an incidental effect of private conduct, they do not constitute 'use or manufacture for the Government' within the meaning of § 1498." (citing *Advanced Software Design Corp. v. Fed. Rsrv. Bank of St. Louis*, 583 F.3d 1371, 1379 (Fed. Cir. 2009))).

Rather than confront the principle articulated in these cases, Moderna's brief seeks to misdirect the Court, suggesting that *Thermalon Industries, Ltd. v. United States*, 34 Fed. Cl. 411 (1995), applies section 1498(a) to the government's purchase of vaccines to eradicate a specific disease. Mot. at 12. Though preceded by a "*Cf*" citation, Moderna's brief does not advise that *Thermalon Industries* has nothing whatsoever to do with the scope of section 1498(a). Instead, though it mentions section 1498 in passing, that case addresses only whether the government had executed a contract for purposes of Court of Federal Claims jurisdiction under a different statutory ground, the Tucker Act, which is governed by a different legal standard. *Thermalon Industries* manifestly did not address the question of whether the government's financial contribution to the purchase of goods used for medical care satisfies the section 1498(a) mandate for sales "for the government." That Moderna chose to suggest otherwise by way of citation to that case, while ignoring the *Larson* precedent that actually addresses section 1498(a), is, charitably put, revealing.

2. The Complaint Plausibly Alleges That Moderna's Infringing Sales Were Not "For the Government"

Under the applicable legal standard, Moderna cannot meet its burden at the pleading stage to show that the government-funded sales of its vaccine—let alone the use by private healthcare workers and individual vaccine recipients, addressed in section VI.A.3—were "for the government."

As the Complaint alleges, "Moderna's vaccine doses made in the United States and

administered in the United States were distributed to hospitals, pharmacies, clinics, and numerous other entities ***for the benefit of individual vaccine recipients in the United States***. All of the manufacturing and sales of vaccines distributed in the United States were ***for the benefit of the American public***." Compl. ¶ 51 (emphasis added). The American people—including private citizens who lined up at drug stores, grocery stores, medical clinics, and hospitals—were the recipients and beneficiaries of the vaccine doses the government purchased. Although Moderna, remarkably, ignores these allegations altogether in its motion, they must be accepted as true, and they are dispositive at the motion to dismiss stage. *See Evancho*, 423 F.3d at 350; *Host Int'l, Inc.*, 32 F.4th at 248; *DelRio-Mocci*, 672 F.3d at 245; *O'Donnell*, 2006 WL 166531, at *7 (denying motion to dismiss where "the allegations in the complaint, which are controlling at this juncture of the litigation, are to the contrary [of defendant's claims]").

The redacted contract that Moderna improperly asks the Court to consider in deciding its motion to dismiss (*see* Section VI.B, *infra*) is not to the contrary. Even accepting it at face value and weighing it against the Complaint's allegations—something this Court cannot do at the pleading stage—the redacted contract provides no basis to refute the Complaint's allegations that the sales of Moderna's vaccine to the government were for the benefit of the individual vaccine recipients, not the government itself. The unredacted portions of the contract merely emphasize the importance of the goal of finding an effective COVID-19 vaccine, Mot. at 11-12, and in fact state that the agreement is "for the United States Government . . . ***and the US population***," with the goal of providing "***nationwide access*** [to the vaccine] as soon as a positive efficacy signal is obtained," *id.* (quoting Mot. Ex. A at 19 C.1.1.1) (emphasis added). Far from conclusively establishing that the intended beneficiary of the contract was the government itself, these excerpts (to say nothing of the additional evidence to which Plaintiffs and the Court lack access, *see* Section

VI.A.4) underscore that the beneficiary of this medical product, as in *Larson*, was the American public.

Eliding this fact, Moderna attempts to shift focus to the importance of the government's policy goal in purchasing COVID-19 vaccines. It posits that, "[s]hort of war, it is difficult to conceive of a situation more within the heart of Section 1498 than the COVID-19 crisis." Mot. at 10. That assertion is unaccompanied by any citation, with good reason: it finds no support anywhere in the law. As the cases above make clear, the lynchpin of the "for the government" inquiry is not whether the infringement at issue implicates an important policy interest or goal of the U.S. government, the standard Moderna invented out of whole cloth and applies throughout its motion. Rather, the legally relevant question, avoided assiduously by Moderna, is whether ***the government itself*** is the beneficiary of that infringing conduct. *See, e.g.*, *Japan Airlines*, 769 F.3d at 1362; *Molinaro v. Watkins-Johnson CEI Div.*, 359 F. Supp. 467, 470 (D. Md. 1973). In that regard, the vaccine sales at issue are nothing like the archetypal section 1498(a) application to military equipment sold to the government, for use by and for the direct benefit of the government. Nor are they even like the sale of desks or windows for use in a government office building.

Under Moderna's invented standard, every government-funded product used to advance any policy goal Congress articulates, or any emergency or "war" it declares—from cancer drugs to fight the war on cancer, to IV needles to fight the war on HIV, to condoms to fight teen pregnancy—would be subject to the draconian liability shield of section 1498(a). No court has so held, and Moderna's argument here would expand the section 1498 defense so dramatically that it would, in essence, permit infringement with impunity for any product purchased, subsidized, or reimbursed by the government with any connection, no matter how tenuous, to any of the innumerable policy goals the government has articulated. That is not the law. As *Larson* and the

cases cited above make clear, "[t]he fact that the government has an interest in the program generally, or funds or reimburses all or part of its costs, is too remote to make the government the program's beneficiary for purposes underlying § 1498." 26 Cl. Ct. at 369. That is especially true in the context of treating and preventing disease. "Medical care is provided for the benefit of the patient, not the government." *Id*. Neither does Moderna point to any authority for the proposition that a national emergency or state of so-called "war" is pertinent to whether the government's funding or reimbursement of vaccines for the general population is "for the government" under section 1498(a). *See* Mot. at 10, 11. The existence of an emergency, even if artificially labelled a "war," does not transform the government into more than an "incidental" beneficiary.

3. The Complaint Plausibly Alleges That Moderna's Inducement of, and Contribution to, Infringing Uses By Healthcare Providers and Individual Vaccine Recipients Was Not "For the Government"

Even were Moderna correct that it can escape liability for its sales to the government (it cannot), Moderna neither acknowledges nor provides any basis to invoke the section 1498(a) defense for the distinct acts of infringement alleged in the Complaint—Moderna's inducement of, and contribution to, infringement by healthcare providers and individual vaccine recipients. In particular, the Complaint alleges that Moderna "actively, knowingly, and intentionally has induced, and continues to induce" infringement of the asserted patents by "encouraging others to . . . use" its infringing COVID-19 vaccine and encouraging healthcare professionals to administer it. Compl. ¶¶ 71, 90, 109, 131, 155, 174. As the Complaint explains, Moderna markets its vaccine to healthcare professionals and instructs them, via standard labeling, to administer those doses to individual recipients nationwide. *Id*. ¶¶ 78-79, 97-98, 119-20, 143-44, 162-63, 182-83. Moderna sought and obtained FDA emergency use authorization and later full-fledged approval for its vaccine for this particular purpose, with the knowledge and intent that the American people would seek and receive its vaccine. *See, e.g.*, *id.* ¶ 16. With respect to these infringing uses (i.e.,

where a healthcare provider injects Moderna's vaccine into a recipient at the local drug store or some other venue), the government plays no role whatsoever, and the notion that this infringement is "for the government" is as implausible as it is unsubstantiated in Moderna's motion.

To the extent Moderna addresses this issue, which independently mandates denial of its motion, it does so on a perfunctory basis in a section entitled "Plaintiffs' Indirect Infringement Allegations Are Also Subject to Section 1498(a)." Mot at 14. That section is utterly bereft of analysis or discussion of how uses of a vaccine by healthcare providers and individual recipients at a CVS possibly could be for the government's direct benefit. And the legal analysis it does include only confirms the inapplicability of section 1498. As Moderna itself explains, "[s]ection 1498 bars indirect infringement claims when the underlying act of infringement is performed by or for the Government," citing as supportive authority *Astornet Technologies*, a case involving use of patented technology ***by the Transportation Security Administration***. Mot. at 14 (citing *Astornet Techs. v. BAE Systems, Inc.*, 802 F.3d 1271, 1277-78 (Fed. Cir. 2015)).

The problem for Moderna is that the "underlying act of infringement" here—unlike in *Astornet Technologies*—is not "performed by or for the government," as Moderna acknowledges is required to invoke section 1498 against a claim of indirect infringement. Rather, it is performed by nongovernmental healthcare providers at grocery stores, drug stores, and doctors' offices across the nation, administering the infringing vaccine into millions of individuals' arms. The government is nowhere to be found in this infringing use. Although the government has subsidized the individuals' infringing use, Moderna provides no basis to contend that these healthcare providers and individuals are acting "for the government," because there is none. Rather, individuals are receiving vaccines for their own benefit, at the direction of Moderna's instructions for use of its infringing product. *See Larson*, 26 Cl. Ct at 269; *Riles*, 999 F. Supp. at 941.

Accordingly, Moderna's section 1498(a) defense cannot succeed as to the Complaint's allegations of infringing uses by healthcare providers and individual vaccine recipients as a matter of law.

4. At the Very Least, Moderna's Motion is Premature

Moderna's motion is not only fatally flawed on the merits, it is also plainly premature. Section 1498(a) is an affirmative defense. As the Third Circuit repeatedly has made clear, "affirmative defenses generally will not form the basis for dismissal under Rule 12(b)(6)." *Stanziale v. Nachtomi (In re Tower Air, Inc.)*, 416 F.3d 229, 242 (3d Cir. 2005); *In re Adams Golf, Inc. Sec. Litig.*, 381 F.3d 267, 277 (3d Cir. 2004) ("[A]n affirmative defense may not be used to dismiss a plaintiff's complaint under Rule 12(b)(6)."). In the specific context of this provision, the Federal Circuit has confirmed that "a defense arising under section 1498(a) should be resolved by summary judgment under Rule 56 rather than a motion to dismiss under Rule 12." *Toxgon*, 312 F.3d at 1382; *see also Advanced Software Design Corp.,* 583 F.3d at 1375 ("When raised between private parties, reliance on § 1498(a) is deemed an affirmative defense.").

That rule makes good sense, particularly here. Discovery may shed light on a host of factual questions impacting the applicability of section 1498(a). For example, Plaintiffs will take discovery on such issues as: (i) the complete and unredacted terms of Moderna's contract with the government and any other related agreements and communications; (ii) the negotiations that culminated in the terms of those agreements; (iii) the nature and extent of the government's involvement in the development and specifications of the vaccine, if any, *cf. Madey v. Duke Univ*., 307 F.3d 1351, 1359 (Fed. Cir. 2002) (reversing and remanding dismissal order in part for further findings on whether university's research grant activities were "for the government"); (iv) how the purchased doses were distributed and to whom—whether to customers of drug stores, grocery stores, private medical practices, or on military bases; and (v) Moderna's and the government's respective understandings of who were the true beneficiaries of the contract, *see Advanced*

Software Design Corp., 583 F.3d at 1376-78 (analyzing correspondence between private party and government agencies in deciding applicability of 1498(a) defense). This information may further demonstrate the inapplicability of section 1498(a).

Moderna has provided no reason to short-circuit this discovery and deprive the Court of a full record when deciding this important issue. Because Moderna filed only a partial motion to dismiss, the relief Moderna seeks here would not remove any issue of infringement, validity, willfulness, or damages from the case. At most, it would change only the quantum of damages. So regardless of the disposition of Moderna's motion, the parties will have to litigate every stage of the merits claim. No count would be dismissed, no issue would be removed, and no discovery relating to validity or infringement would be avoided.

B. Moderna Cannot Establish at the Pleading Stage That Its Infringement was with the Government's "Authorization or Consent" Under 28 U.S.C. § 1498(a)

Moderna also cannot meet its burden to establish the "authorization or consent" prong of section 1498(a) at the pleading stage, a failure that independently merits denial of its motion. Here, again, Moderna relies on a selective excerpt of a heavily redacted contract with the government.

In so doing, Moderna plainly exceeds the bounds of what is proper on a motion to dismiss. While courts may take judicial notice of the fact or existence of a document or its contents, "[t]he truth of the content, and the inferences properly drawn from them . . . is not a proper subject of judicial notice under Rule 201." *IV Sols.*, 2017 WL 3018079, at *2; *see also Network Managing Sols., LLC*, 2017 WL 5195863, at *4 ("Taking judicial notice of the truth of the documents' contents could breach the boundaries of judicial notice."); *In re Peregrine Sys., Inc.*, 311 B.R. 679, 692 (D. Del. 2004) (same).[4] Yet, both here and on the "for the government" prong, Moderna asks

[4] None of the cases Moderna cites are to the contrary. *See Williams v. Magee*, No. 1:19-CV-720, 2019 WL 3337085, at *4 (M.D. Pa. July 24, 2019) (judicial notice of which entity provided

the Court to find truth in, and draw inferences from, the limited portions of the heavily redacted Exhibit A that are visible. With good reason, courts regularly decline to take judicial notice of redacted documents when deciding a motion to dismiss. *IV Sols.*, 2017 WL 3018079, at *2-3; *Phillips*, 2020 WL 3128595, at *3; *Se. Ready Mix, LLC*, 2018 WL 8263138, at *9.

Thus, while it is true that an unredacted portion of Exhibit A incorporates the FAR 52.227-1 authorization and consent clause, Mot. at 12-13 (citing Ex. A at 46), neither the Court nor Plaintiffs have any way of understanding the full context of that statement, which may have been modified, limited, or conditioned in the redacted parts of Exhibit A—or in another document entirely. As just one potential example, the government may have clarified that its authorization or consent does not apply to willful patent infringement by Moderna, which is what Plaintiffs allege here. Indeed, a court has declined even to grant summary judgment where, as here, the information of record was insufficient to preclude factual questions as to whether FAR 52.227-1 actually applied to the contracts at issue, despite being invoked specifically in several of them. *See Leupold & Stevens, Inc. v. Lightforce USA, Inc.*, 449 F. Supp. 3d 1015, 1021 (D. Or. 2020).

In that regard, it is telling that the government has not filed a Statement of Interest in this case or otherwise indicated to the Court that it agrees with Moderna that Plaintiffs' claims fall within the ambit of section 1498(a). While not dispositive, courts frequently look to the government's position for evidence on the "authorization or consent" prong. *See Japan Airlines*,

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services to the government under a contract); *Inman v. Technicolor USA, Inc*., No. CIV.A. 11-666, 2011 WL 5829024, at *4 (W.D. Pa. Nov. 18, 2011) (judicial notice of website user agreement where plaintiff's complaint relied on website but not specifically user agreement); *London v. Delaware Dep't of Corr.*, No. CV 19-1518-MN-SRF, 2021 WL 3422360, at *7 (D. Del. Aug. 5, 2021), *report and recommendation adopted*, No. CV 19-1518 (MN), 2021 WL 4262458 (D. Del. Sept. 20, 2021) (judicial notice of website showing fact of a job vacancy at a government agency); *Novartis Pharms. Corp. v. Handa Neuroscience, LLC*, No. CV 21-645-LPS, 2022 WL 610771, at *4 (D. Del. Mar. 1, 2022) (judicial notice of certain facts in securities filings); *Southmark Prime Plus, L.P. v. Falzone*, 776 F. Supp. 888, 892 (D. Del. 1991) (judicial notice of "facts").

769 F.3d at 1363 (noting "that the United States has unequivocally stated its position that suit under § 1498(a) is appropriate here"); *Arlton v. Aerovironment, Inc.*, No. 2:20-CV-07438-AB-GJS, 2021 WL 1589302, at *9 (C.D. Cal. Apr. 22, 2021) ("[T]he Government also filed a Statement of Interest in this case providing express consent to the accused activities.").[5]

As with the "for the government" prong, Moderna has failed to meet its burden to establish that the "authorization or consent" prong applies at the pleading stage.

VII. CONCLUSION

For the above reasons, "accept[ing] as true all allegations and all reasonable inferences" in the Complaint, *Evancho*, 423 F.3d at 350, Plaintiffs' claims against Moderna do not "lack facial plausibility," *Ehrlich v. Alvarez*, 2022 WL 1487021, *2 (3d Cir. May 11, 2022). Although Moderna's decision to file this motion without legal support is at first blush perplexing, there is a simple explanation: Moderna's preferred defense to the infringement claims asserted here—that the patents are obvious—has failed both before the PTO and the Federal Circuit, and it is estopped statutorily from raising that defense against the claims upheld in those proceedings. With its arsenal nearly empty, Moderna beseeches the Court to expand the section 1498(a) defense, hoping that it can escape liability so the government can attempt to advance defenses Moderna cannot. Put another way, were Moderna's substantive defenses viable, it likely would not attempt to shift liability to the very government that enriched it enormously. Section 1498 is not Moderna's "insurance plan" for its willful infringement of Plaintiffs' patents, *Riles*, 999 F. Supp. at 940.

[5] Moderna also cites a Declaration from its Senior Vice President and Deputy General Counsel, Shaun Ryan, stating his belief that Moderna's sales to the government "are subject to 28 U.S.C. 1498(a)." Mot. 6-7 n.6. Needless to say, Moderna's in-house attorney's untested, self-serving beliefs about the scope of section 1498(a) do not justify dismissal. That is a question for the Court or jury to decide, on the basis of a full record that includes discovery and cross-examination.

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